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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,867	09/19/2003	Ann Marie Schmidt	55873-BA-PCT-US/JPW/AJM/A	6756

7590 09/18/2006

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EXAMINER

EMCH, GREGORY S

ART UNIT PAPER NUMBER

1649

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,867	<b>Applicant(s)</b> SCHMIDT ET AL.	
	<b>Examiner</b> Gregory S. Emch	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

Claim 17 has been amended as requested in the amendment filed on 30 June 2006.

Following the amendment, claim 17 is pending and under examination in the instant office action.

The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

### ***Claim Rejections - 35 USC § 112, first paragraph***

The rejection of claim 17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is maintained for reasons of record and as set forth *infra*.

The claim is drawn to an isolated antibody immunoreactive with an epitope comprising a unique sequence present within the EN-RAGE molecule having the amino acid sequence set forth in SEQ ID NO: 2.

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In the reply filed 30 June 2006, Applicants assert "that claim 17, as amended, provides an isolated antibody immunoreactive with an epitope comprising a unique sequence present within the EN-RAGE molecule having the amino acid sequence set forth in SEQ ID NO: 2. Accordingly, one skilled in the art would reasonably believe that the inventors, at the time the application was filed, had possession of the claimed invention."

Applicants' arguments have been fully considered and are not found persuasive.

As set forth in the previous office actions dated 14 October 2005 and 28 March 2006, the prior art teaches antibodies to a peptide comprising a sequence that is 92% identical to Applicants' SEQ ID NO: 2 and contains scattered mismatched residues (at positions 14, 30, 36 and 47) when compared to Applicants' SEQ ID NO: 2. Further, cross-reactivity of antibodies is a common occurrence, especially in antibodies that bind to similar proteins. Accordingly, U.S. Patent No. 6,787,637 to Schenk discloses that when an antibody is said to bind to an epitope within specified residues, it does not necessarily contact every single amino acid residue within the epitope; nor does every amino acid substitution or deletion within the epitope necessarily affect binding (col. 14, lines 1-8). Thus, if the skilled artisan raised antibodies against Applicant's SEQ ID NO: 2 and against the peptide of Hitomi et al., the pool would contain identical antibodies. Therefore, Applicants are not in possession of an isolated antibody immunoreactive with an epitope comprising "unique" epitopes that are present in the remaining 8% of the EN-RAGE molecule.

***Claim Rejections - 35 USC § 112, second paragraph***

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record and as set forth *infra*.

The claim is drawn to an isolated antibody immunoreactive with an epitope comprising a unique sequence present within the EN-RAGE molecule having the amino acid sequence set forth in SEQ ID NO: 2.

In the reply filed 30 June 2006, Applicants assert that the term "unique," when read in the context of claim 17, is not indefinite and that the skilled artisan would understand the isolated antibody to be immunoreactive with an epitope present in SEQ ID NO: 2 but not present in a non-EN-RAGE protein.

Applicants' arguments have been fully considered and are not found persuasive. As set forth in the previous office actions dated 14 October 2005 and 28 March 2006 (and *supra*), the prior art teaches antibodies to peptides comprising sequences that are 92% identical with scattered mismatched residues when compared to Applicants' SEQ ID NO: 2. Further, cross-reactivity of antibodies is a common occurrence, especially in antibodies that bind to similar proteins. Thus, if the skilled artisan raised antibodies against Applicant's SEQ ID NO: 2 and against the peptide of Hitomi et al., the pool would contain identical antibodies. Therefore, it is unclear how a unique epitope would exist in the remaining 8% of the polypeptide. That is, the skilled artisan would not

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comprehend what "unique" epitopes would be present in the remaining 8% of the EN-RAGE molecule.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

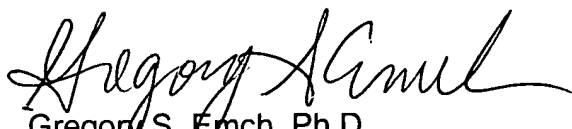
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gregory S. Emch, Ph.D.  
Patent Examiner  
Art Unit 1649  
06 September 2006

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER